IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

UNITED STATES OF AMERICA Plaintiff, v. SAGE PHARMACEUTICALS, INC. a corporation, an JIVN REN CHEN, and CHARLES L. THOMAS, individuals Defendants.	CIVIL NO. 13-cv-1983 JUDGE HICKS MAGISTRATE JUDGE HORNSBY

ANSWER TO COMPLAINT FOR PERMANENT INJUNCTION

NOW INTO COURT, through undersigned counsel, come Defendants Sage Pharmaceuticals, Inc. (ñSageò), Jivn Ren Chen (ñChenò), and Charles L. Thomas (ñThomasò) (collectively, ñdefendantsò), who, in answer to plaintiffôs Complaint, deny each and every allegation contained therein, except such as may be hereinafter specifically admitted, and without waiving any motions, exceptions or defenses, answer each separately numbered paragraph of the Complaint, as follows:

Introduction

1. This action is brought by the United States of America (hereinafter ñPlaintiffò) pursuant the Federal Food, Drug, and Cosmetic Act (the ñActò), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to enjoin and restrain Sage Pharmaceuticals, Inc., a corporation (ñSageò), and Jivn Ren Chen and Charles L. Thomas, individuals (hereinafter, collectively, ñDefendantsò) from violating:

a. 21 U.S.C. § 331 (d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce any new drug within the meaning of 21 U.S.C. § 321 (p) that is neither approved under 21 U.S.C. § 355 (a), nor exempt from approval pursuant to 21 U.S.C. § 355 (i);

b. 21 U.S.C. § 331 (a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352 (f)(1); and

c. 21 U.S. C. § 331 (k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352 9f)(1).

ANSWER: The allegations in paragraphs 1a. through 1c. set forth the nature and basis of this lawsuit to which no response is required. To the extent that a response is deemed required, defendants deny same.

Jurisdiction and Venue

2. This court has jurisdiction over this matter pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

ANSWER: The allegations contained in paragraph 2 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391 (b).

ANSWER: The allegations contained in paragraph 3 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

Defendants

4. Defendant Sage is incorporated under the laws of Louisiana, and does business at 5408 Interstate Drive, Shreveport, LA 71109, within the jurisdiction of this Court. Sage manufactures, processes, labels, holds, and distributes drugs.

ANSWER: Defendant Sage admits the allegations set forth in paragraph 4.

5. Defendant Jivn Ren Chen is the President of Sage. He is responsible for overseeing the overall operations of Sage, including sales, manufacturing, quality assurance, and finances. He has the duty, power, and responsibility to prevent, detect, and correct violations.

ANSWER: Defendant Chen admits that he is president of Sage, and denies the remaining allegations set forth in paragraph 5.

6. Defendant Charles L. Thomas is the Director of Corporate Quality at Sage. He has been present for establishing and maintaining the quality assurance system at the firm. He has been present at all FDA inspections, and regulatory meeting where unapproved new and misbranded drugs were discussed. He also has the duty, power, and responsibility to prevent, detect, and correct violations.

ANSWER: Defendant Thomas admits only that he is the current Director of Corporate Quality at Sage, and denies the remaining allegations set forth in paragraph 6.

7. Defendants have been and are now engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing in interstate commerce several products, including pain relievers, cough and cold remedies, and topical wound cleansers that are drugs within the meaning of 21 U.S.C. § 321 (g).

ANSWER: Defendants admit only that they have been and are now engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing certain products. The remaining allegations contained in paragraph 7 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

Defendant's Violations

8. Defendantôs products are drugs within the meaning of 21 U.S.C. § 321 (g) because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and/or are intended to affect the structure or any function of the human body.

ANSWER: The allegations contained in paragraph 8 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

9. Defendants regularly manufacture drugs using components they receive in interstate commerce and introduce finished drug products into interstate commerce for shipment outside the state of Louisiana.

ANSWER: Defendants deny the allegations set forth in paragraph 9.

9. (sic) The United State Food and Drug Administration (ñFDAò) inspected Defendantsô facility most recently between February 14 ï 17, 2012 (ñFebruary 2012 Inspectionò).

ANSWER: Defendants admit the allegations set forth in this paragraph 9.

10. The February 2012 Inspection revealed that Defendants manufacture and distribute into interstate commerce the following drug products:

a. Relagesic, which is a prescription pain reliever;

b. Ru-Hist D tablets and Ru-Hist D liquid, which are over-the-counter

c. (ñOTCò) cough and cold remedies; and

d. Septicare Wound Cleanser and Deodorant (ñSepticareò) and Perifoan

e. Anti-Bacterial Cleanser (ñPerifoamò), which are topical skin cleansers.

ANSWER: Defendants deny the allegations set forth in paragraph 10.

11. During the February 2012 Inspection, FDA investigations also observed that Sage had manufactured Nu-COPD and Ru-Hist Plus, two OTC cough and cold remedies, but had not yet distributed these products. Defendant Thomas state that Sage planned to distribute all inventory on site.

ANSWER: Defendants deny the allegations set forth in paragraph 11.

12. During the February 2012 Inspection, Defendants also stated that they were no longer manufacturing the pain reliever Dolorex. However, when FDA returned to collect samples in June 2012, investigators found that Sage manufactured Dolorex in March 2012.

ANSWER: Defendants deny the allegations set forth in paragraph 12.

Defendants' Products are Unapproved New Drugs

13. Defendants have been and are now engaged in the manufacture, processing, packing, labeling, holding, or distributing of numerous unapproved new drugs that they introduce or cause to be introduced into interstate commerce, in violation of 21 U.S.C. § 331 9d). These unapproved new drugs include, but are not limited to: Relagesic, Dolorex, Ru-Hist Plus, Ru-Hist D tablets, Ru-Hist D liquid, Nu-COPD, Septicare, and Perifoam.

ANSWER: The allegations contained in paragraph 13 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

14. FDA has conducted a search of its records for New Drug Application (ñNDAò), Abreviated New Drug Application (ñANDAò), and Investigational New Drug Application (ñINDò) submissions by Defendants. FDA has ascertained that Defendants have no approvals on file of an NDA, ANDA, or IND for any of the eight drugs listed above.

ANSWER: Defendants are without knowledge and information sufficient to form a belief as

to the truth of the allegations set forth in paragraph 14, and therefore deny same.

15. A ñnew drugò is defined as any drug ñthe composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.ò 21 U.S.C. § 321 9p)(1).

ANSWER: The allegations contained in paragraph 15 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

16. For a product to be deemed ñgenerally recognized as safe and effectiveò (ñGRAS/GRAEò), it must: (1) have substantial evidence of safety and effectiveness, or (2) if it is an OTC drug, comply with a monograph established pursuant to an FDA regulation. 21 U.S.C. § 355 (d); 21 C.F.R. § 330.1.

ANSWER: The allegations contained in paragraph 16 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

17. Based upon searches of the publically available medical and scientific literature, FDA has determined that there are no published adequate and well-controlled investigations or any other scientific literature demonstrating that Defendantsô drug products are GRAS/GRAE for any use. Because there are no adequate and well-controlled investigations of the intended use of these drugs, qualified experts.

ANSWER: Defendants are without knowledge and information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17, and therefore deny same.

18. Also, a drug product may be deemed GRAS/GRAE, and thus marketed without an approved NDA, ANDA, or IND application, if the drug is manufactured and distributed in strict compliance with an OTC monograph. 21 C.F.R. § 330.1. With respect to OTC drugs, FDA has reviewed the active ingredients and the labeling for over 80 therapeutic classes of drugs. For each of these categories, FDA has published an OTC drug monograph in the Federal Register. OTC drug monographs clearly identity acceptable ingredients, doses, formulations, and labeling for specific active ingredients used in OTC drug products.

ANSWER: Defendants are without knowledge and information sufficient to form a belief as to the truth of the allegation concerning FDAôs review related to OTC drugs. The remaining allegations in paragraph 18 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

19. Defendantsô two OTC topical wound cleansers, Septicare and Perifoam, do not conform to any OTC monograph set forth in 21 C.F.R. § 330.1.

ANSWER: The allegations contained in paragraph 19 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

20. Although there are monographs for cold/cough remedies-see 21 C.F.R. Part 341, Cold, Cough, Allergy, Bronco-dialator, and Antiasthmatic Drug Products for Over-the-Counter Human Use ï none of Defendantsô four OTC cough and cold drug products conform to it.

ANSWER: The allegations contained in paragraph 20 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

21. For example, Ru-Hist D tablets, Ru-Hist D liquid, and Ru-Hist Plus contain a nasal decongestant- phenylephrine hydrochloride ï and antihistamine ï pyrilamine maleate. Under the applicable OTC monographs, phenylephrine hydrochloride is to be taken every 4 hours, see 21 C.F.R. § 341.80(d)(1), and pyrilamine maleate is to be taken every 6-8 hours, see 21 C.F.R. § 342.72 (d)(11). Thus, Ru-Hist D tablets, Ru-Hist D liquid, and Ru-Hist Plus cannot meet the applicable OTC monographs because there is no way to write adequate directions for use that would be meet the dosage interval requirements for each of the active ingredients according to their respective monographs.

ANSWER: The allegations contained in paragraph 21 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same. Further answering, defendants affirmatively allege that the complaint misstates the labeling requirements contained in the applicable OTC monograph by omitting reference to CFR sections that permit the combination of ingredients when the time intervals for administration of the individual ingredients differ.

22. In addition, Nu-COPD does not meet the applicable monographs for its active ingredients, phenylephrine hydrochloride, see 21 C.F.R. § 341,80(d)(1), and guaifenesin, see 21 C.F.R. § 341.76(d). Both ingredientsô monographs require dosing every four hours, and Nu-COPDôs label states that the product can be dosed every four to six hours.

ANSWER: The allegations contained in paragraph 22 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

23. Accordingly, by manufacturing and distribution these unapproved new drugs, Defendants introduce unapproved new drugs, or cause them to be introduced, into interstate commerce, in violation of 21 U.S.C. § 331(d).

ANSWER: The allegations contained in paragraph 23 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

Defendants' Products Are Misbranded Drugs

24. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear ñadequate directions for use.ò Pursuant to 21 C.F.R. § 201.5, ñadequate directions for useò are defined as ñdirections under which the layman can use a drug safely and for the purpose for which it is intended.ò Adequate directions for use must be based on animal and clinical data derived from extensive, scientifically controlled testing.

ANSWER: The allegations contained in paragraph 24 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

25. It is not possible to write such directions for Defendantsô drugs listed above, because adequate directions for drug use ï including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures ï are necessarily premised on animal and clinical data derived from extensive, scientifically controlled testing.

ANSWER: The allegations contained in paragraph 25 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

26. Defendants do not have any well-controlled clinical test data for the eight drugs listed above. Consequently, adequate directions under which a layman can safely use these drugs cannot be written. Moreover, because the products at issue are unapproved new drugs, as described above, these drugs are not exempt from the requirement for adequate directions for useï 21 C.F.R. §§ 201.100(c)(2), 201.115.

ANSWER: The allegations contained in paragraph 26 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same.

27. Furthermore, Ru-Hist D tablets, Ru-Hist D liquid, Ru-Hist Plus, and Nu-COPD are misbranded because the dosage intervals provided on their labels do not strictly adhere to the dosage intervals listed in the relevant FDA OTC monographs.

ANSWER: Defendants deny the allegations set forth in paragraph 27.

28. Defendants violate 21 U.S.C. § 331 (a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352 9f)(1).

ANSWER: Defendants deny the allegations set forth in paragraph 28.

29. Defendants violate 21 U.S.C. § 331 (k), by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 3519f)(1).

ANSWER: Defendants deny the allegations set forth in paragraph 29.

History of Violations

30. Defendants are aware that their conduct violates the law and that continued violations could lead to regulatory action.

ANSWER: Defendants deny the allegations set forth in paragraph 30.

31. In 1998, the United States of America sought to enjoin Sage for violations of FDAôs current good manufacturing regulations and for distributing unapproved new drugs.

ANSWER: Defendants admit only that the U.S.A. sought injunctive relief against Sage, but deny the remaining allegations of this paragraph.

32. In 2000, as a result of that injunction action, the Court issued an order, requiring Sage to cease manufacturing and distributing two specific unapproved new drugs at issue in that caseð Palgic D and Palgic DSð until FDA approval of an NDA for those products.

ANSWER: Defendants admit only that the Court issued an order, and further answering, states that the order speaks for itself. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of the order, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

33. Since the entry of that order, Defendants have refused to cease manufacturing and distributing other unapproved new and misbranded drugs, despite various warnings from FDA.

ANSWER: The allegations contained in paragraph 33 include argument and not allegations of fact to which a response is required. To the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

34. FDA has issued repeated warnings over the last thirteen years during in-person meetings and in written letters. Defendants have responded to the agencyôs letters and meetings with promises to stop manufacturing certain unapproved products, promises to file applications for approval for specific products; and claims that FDA is incorrect about the interpretation of its regulations.

ANSWER: The allegations contained in paragraph 34 refer to conversations and documents that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those conversations and documents, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

35. At a prior FDA inspection between May 2-6, 2011, FDA investigators informed Defendants that they were distributing unapproved new and misbranded drugs. Defendants did not respond orally to this information at the May 2011 inspection. In their written responses to the May 2011 inspection, however, they stated that they would cease manufacturing and distributing Relagesic.

ANSWER: The allegations contained in paragraph 35 refer to conversations and documents that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those conversations and documents, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

36. At the February 2012 Inspection, the FDA investigator collected evidence that Defendants continued to manufacture and distribute Relagesic.

ANSWER: The allegations contained in paragraph 36 refer to conversations and documents provided to or obtained by FDA in connection with its investigation that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those conversations and documents, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

37. During the February 2012 Inspection, Defendants stated that they no longer manufactured Dolorex.

ANSWER: The allegations contained in paragraph 37 refer to conversations and documents that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those conversations and documents, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

38. When FDA returned to collect samples in June 2012, investigators found that Sage had manufactured Dolorex in March 2012.

ANSWER: The allegations contained in paragraph 38 refer to conversations and documents provided to or obtained by FDA in connection with its investigation that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those conversations and documents, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

39. FDA informed Defendants that they are manufacturing and distributing unapproved new and misbranded drugs in letters dated January 13, 2012, December 14, 2011, September 28, 2011, November 21, 2007, August 28, 2007, January 29, 2007, and June 23, 1999. Several of those letters specifically state that Septicare and Relagesic are unapproved new drugs.

ANSWER: The allegations contained in paragraph 39 refer to documents that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those documents, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

40. Defendants also received a Warning Letter dated October 11, 2002 that warned Defendants that the extended release guaifenesin tablets they were manufacturing at the time were unapproved new drug products that could be subject to an enforcement action.

ANSWER: The allegations contained in paragraph 40 refer to documents that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those documents, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

41. The agency also held meetings with Defendants on September 15, 2011, July 31, 2000, and January 13, 2000 to discuss the firmôs manufacture and distribution of unapproved new and misbranded drugs, including Septicare, Relagesic, and Perifoam.

ANSWER: The allegations contained in paragraph 41 refer to conversations that speak for themselves and are subject to interpretation, and include argument and not allegations of fact to which a response is required. To the extent that plaintiffôs allegations conflict with or mischaracterize the content of those conversations, and/or to the extent that a response to the allegations of this paragraph are deemed required, defendants deny same.

42. Although Defendants stopped manufacturing particular products, such as the products that were the subject of the previous injunction and the October 11, 2002 Warning

Letter, they began manufacturing different unapproved new and misbranded drugs to take the place of the discontinued products.

ANSWER: Defendants deny the allegations contained in paragraph 42.

43. As demonstrated by the results of FDAôs most recent inspection, Defendants continue to violate the Act, by inter alia continuing to manufacture Septicare, Relagesic, and Perifoam, despite numerous warnings from FDA that these products are illegal.

ANSWER: Defendants deny the allegations contained in paragraph 43.

44. Based on Defendantsô course of conduct throughout the past thirteen years and the results of FDAôs inspections, Plaintiff is informed and believes that, unless restrained by order of this Court, Defendants will continue to distribute unapproved new and misbranded drugs in violation of the Act, 21 U.S.C. § 331(a) and (d), and to cause drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 331 (k).

ANSWER: The allegations contained in paragraph 44 set forth legal conclusions to which no response is required. To the extent that a response is deemed required, defendants deny same. Further answering, defendants affirmatively deny that injunctive relief is appropriate in this case.

AFFIRMATIVE DEFENSES

Defendants set forth their affirmative defenses to the complaint, as follows:

1. Plaintiffôs Complaint fails to state claims upon injunctive or other relief can be granted.
2. Plaintiffôs claims, in whole or in part, are barred by the applicable statute of limitations.
3. Plaintiffôs claims, in whole or in part, are barred by the doctrine of laches.
4. Plaintiffôs claims are improperly brought before this court, in that a prior action remains pending in the Western District of Louisiana which concerns the same subject matter and is the proper forum for the present dispute.

WHEREFORE, DEFENDANTS SAGE, CHEN AND THOMAS, collectively and individually, respectfully request that the court deny the relief sought by plaintiff, dismiss the complaint in its entirety and/or enter judgment on defendantsô behalf, and award defendants such other relief as the court deems just and proper.

DATED this 9th day of September, 2013

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Answer has been served on all counsel of record through the Courtôs ECF system.

/s/ M. Thomas Arcneaux
OF COUNSEL